

REMARKS

This Response is being filed in connection with the Office Action mailed June 16, 2003. Claims 3 to 6, 8, 10 to 13, 15, 17, 18, 20, 22 to 26, 30 to 61, 65 and 66 are pending. Claims 30 to 61 stand withdrawn as directed to a non-elected invention. Claim 66 has been allowed. By the present Response, claims 4, 5, 10 to 13, 15, 17, 18, 20, 22 and 27 have been canceled without prejudice. Applicants' maintain the right to prosecute the canceled claims in any related application claiming the benefit of priority of the subject application. New claims 67 to 78 have been added. Accordingly, upon entry of the Response, claims 3, 6, 8, 23 to 26 and 65 to 78 are under consideration.

Regarding the Amendments to the Specification

The specification has been amended at page 38 to insert a paragraph that recites the name and address of the depository and the deposit dates for various hybridomas and heavy and light chain variable regions. This amendment and the biological deposits do not create any presumption that the deposited material is required to satisfy 35 U.S.C. §112. Access to the deposits is as set forth under 37 C.F.R. §1.808(a) and (b). The specification has also been amended at pages 39, 43, 44 and 46 to insert a trademark symbol, "TM," where appropriate.

Thus, the amendments to the specification were made to address various informalities. As such, no new matter has been added and entry thereof is respectfully requested.

Regarding the Claim Amendments

The amendments to claims 6, 8, 23 to 25 and 65 were made to address two informalities. In particular, claims 6, 8 and 23 to 25 have been amended to depend solely from claim 3 instead of claims 3 to 5 in view of the cancellation of claims 4 and 5. Claim 65 has been amend to delete the recitation of antibody sequences deposited as plasmids in favor of new claim 67. Thus, as the claim amendments were made to address mere informalities, no new matter has been added and entry thereof is respectfully requested.

Regarding the New Claims

New claims 67 to 78, are supported throughout the specification. In particular, claim 67, directed to human monoclonal antibodies comprising heavy-chain variable sequence and light-chain variable sequences encoded by particular sequences; F2-103-H (ATCC PTA-3302) and F2-103-L (ATCC PTA-3303); F5-77-H (ATCC PTA-3304) and F5-77-L (ATCC PTA-3305); and F5-157-H (ATCC PTA-3306) and F5-157-L (ATCC PTA-3307), is supported, for example, as set forth in the Response filed March 20, 2003, for claim 65, and at page 44, line 22, to page 45, line 52, which discloses the recited antibody encoding sequences. Claims 68 to 78, directed to hybridomas having ATCC Nos. PTA-2308, PTA-2309, PTA-3337 and PTA-3338, and cell lines having ATCC Nos. PTA-3302, PTA-3303, PTA-3304, PTA-3305, PTA-3306 and PTA-3307, are supported, for example, by claim 3 originally filed, which recites the corresponding hybridoma/antibody designations: no. 11 (PTA-2308); no. 72 (PTA-2309); F1-102 (PTA-3337); F4-465 (PTA-3338); F2-103 (PTA-3302 and -3303); F5-77 (PTA-3304 and -3305); and F5-157 (PTA-3306 and -3307). Claims 68 to 78 are also supported, for example, at page 44, line 20, to page 45, line 52, which discloses the heavy and light chain sequences of F2-103; F5-77; and F5-157. Thus, as claims 67 to 78 are supported by the specification, no new matter has been added and entry thereof is respectfully requested.

Regarding the Oath/Declaration

A Supplemental Declaration is submitted herewith under 37 C.F.R. §1.67(a). The Supplemental Declaration includes mailing addresses for each inventor under 37 C.F.R. §1.63(c)(1), and includes a ZIP code designation. The Supplemental Declaration meets the requirements under 37 C.F.R. §1.63. Accordingly, acceptance of the Supplemental Declaration is respectfully requested.

I. REJECTIONS UNDER 35 U.S.C. §112

The rejection of claims 3 to 6, 8, 10 to 13, 15, 17, 18, 20, 22 to 26, and 65, under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed. The Examiner requests that the specification be amended to recite the date of deposit and name and address of the depository.

Claims 4, 5, 10 to 13, 15, 17, 18, 20, and 22 have been canceled herein without prejudice. Accordingly, the rejection as to these claims is moot.

As to the remaining claims, as set forth above the specification has been amended to recite deposit dates and the name and address of the depository. This amendment and the biological deposits do not create any presumption that the deposited material is required to satisfy 35 U.S.C. §112. Access to the deposits is as provided under 37 C.F.R. §1.808(a) and (b). Accordingly, in view of the amendment, Applicants respectfully request that the rejection under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement, be withdrawn.

The rejection of claims 25 and 26 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement is respectfully traversed.

Although originally filed claims 25 and 26 are adequately enabled by the specification, Applicants have amended claims 25 and 26 to directly or indirectly depend solely from claim 3. In this regard, the Examiner acknowledges that the specification is enabling for “nucleic acids that encode[s] the antibodies and host cells that express said nucleic acids produced by the specific hybridomas in claim 3.” [see the Office Action at page 3, section 8] Thus, since claims 25 and 26, as amended, depend solely from claim 3, the rejection is moot. Accordingly, Applicants respectfully request that the rejection of claims 25 and 26 under 35 U.S.C. §112, first paragraph, as allegedly lacking enablement, be withdrawn.

The rejection of claims 25 and 26 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description is respectfully traversed.

Although originally filed claims 25 and 26 are adequately described such that the skilled artisan would recognize that Applicant's had possession of the claimed subject matter, claims 25 and 26 have been amended to depend solely from claim 3. In this regard, the Examiner acknowledges that the “isolated nucleic acids encoding the specific antibodies/hybridomas recited in claims 3-5 meet the written description provision of 35 USC 112, first paragraph.” [see the Office Action at page 5, 3rd paragraph] Thus, since amended claims 25 and 26 depend solely from claim 3, the rejection is moot. Accordingly, Applicants respectfully request that the

rejection of claims 25 and 26 under 35 U.S.C. §112, first paragraph, as allegedly lacking an adequate written description, be withdrawn.

The rejection of claims 5, 6, 8, 10 and 23 to 26 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is respectfully traversed. The claims stand rejected due to various alleged ambiguities in the claim language.

Claims 5, 6, 8, 10 and 23 to 26 are clear and definite as written. Nevertheless, solely in order to further prosecution of the subject application and without conceding that the rejection is in any way proper, claims 5 and 10 have been canceled herein without prejudice rendering the rejection moot. In addition, claims 6, 8 and 23 to 26 have been amended as set forth above removing all grounds for this rejection. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §112, second paragraph, be withdrawn.

II. REJECTIONS UNDER 35 U.S.C. §§102(e) and 103(a)

The rejection of claims 4, 5, 6, 11, 18, 20 and 22 to 26 under 35 U.S.C. §102(e) as allegedly anticipated by Kucherlapati *et al.* (U.S. Patent No. 6,150,584) alone and in further evidence of deBoer (U.S. Patent No. 5,874,082) is respectfully traversed. Allegedly Kucherlapati *et al.* describe human antibodies against CD40. deBoer allegedly "disclose that all anti-CD40 known in the art have a stimulatory effect on B cells." [see the Office Action at page 7, 5th paragraph]

Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration (*In re Spada*, 15 USPQ 2d 1655 (Fed. Cir. 1990); *In re Bond*, 15 USPQ 2d 1566 (Fed. Cir. 1990)).

Claims 4 to 6, 11, 18, 20 and 22 to 26 are not anticipated by Kucherlapati *et al.* (U.S. Patent No. 6,150,584). Nevertheless, solely in order to further prosecution of the subject application and without conceding that the rejection is in any way proper, claims 4, 5 11, 18, 20 and 22 have been canceled herein without prejudice rendering the rejection moot.

Originally filed claims 6 and 23 to 26 are also not anticipated by Kucherlapati *et al.* (U.S. Patent No. 6,150,584). As to deBoer (U.S. Patent No. 5,874,082), this reference does not teach

originally filed claims 23 to 26, nor does it provide that which the Patent Office alleges as to these claims. In this regard, Applicants disagree with the Patent Office's characterization of the deBoer patent and the propriety of combining this reference with Kucherlapati *et al.* under 35 U.S.C. §102.

Nevertheless, solely in order to further prosecution of the subject application and without conceding that the rejection is in any way proper, claims 6 and 23 to 26 have been amended to directly or indirectly depend solely from claim 3. In view of the amendment to claims 6 and 23 to 26 the rejection is moot. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §102(e), as allegedly anticipated by Kucherlapati *et al.* (U.S. Patent No. 6,150,584) be withdrawn.

The rejection of claims 4 to 6, 8, 10 to 13, 15, 17, 18, 20 and 22 to 26 under 35 U.S.C. §103(a) as allegedly unpatentable over Kucherlapati *et al.* (U.S. Patent No. 6,150,584) in view of deBoer (U.S. Patent No. 5,874,082) is respectfully traversed. Allegedly these claims would have been obvious at the time of the invention in view of Kucherlapati *et al.* and deBoer.

Claims 4 to 6, 8, 10 to 13, 15, 17, 18, 20 and 22 to 26 would not have been obvious in view of Kucherlapati *et al.* (U.S. Patent No. 6,150,584) alone, or in combination with deBoer (U.S. Patent No. 5,874,082). Nevertheless, solely in order to further prosecution of the subject application and without conceding that the rejection is in any way proper, claims 4, 5 10 to 13, 18, 20 and 22 have been canceled herein without prejudice rendering the rejection moot. In addition, claims 6, 8 and 23 to 26 have been amended to directly or indirectly depend solely from claim 3. In view of the amendment to claims 6, 8 and 23 to 26 the rejection is moot. Accordingly, Applicants respectfully request that the rejection under 35 U.S.C. §103(a) be withdrawn.

CONCLUSION

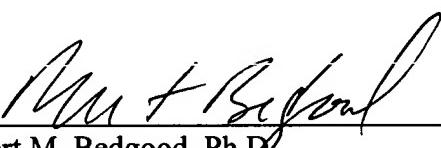
In summary, for the reasons set forth herein, Applicants maintain that claims 3, 6, 8, 23 to 26 and 65 to 78 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any additional fees, or make any credits, to Deposit Account No. 50-2212.

Respectfully submitted,

Date: 12-9-03



Robert M. Bedgood, Ph.D.
Reg. No. 43,488
Agent for Applicant

PILLSBURY WINTHROP LLP
11682 El Camino Real, Suite 200
San Diego, CA 92130-2593
Telephone: (858) 509-4065
Facsimile: (858) 509-4010